UNITED STATES DEPARTMENT OF COMMERCE United States Patent and Trademark Office Address: COMMISSIONER FOR PATENTS P.O. Box 1450 Alexandria, Virginia 22313-1450 www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/598,965	02/26/2007	Jean Gariepy	MMC.P-002	2679
57381 Larson & Ande	7590 02/24/200 rson, LLC	9	EXAM	INER
P.O. BOX 4928		STEELE, AMBER D		
DILLON, CO 8	80433		ART UNIT	PAPER NUMBER
			1639	
			MAIL DATE	DELIVERY MODE
			02/24/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

	Application No.	Applicant(s)				
Office Action Comments	10/598,965	GARIEPY ET AL.				
Office Action Summary	Examiner	Art Unit				
	AMBER D. STEELE	1639				
The MAILING DATE of this communication app Period for Reply	ears on the cover sheet with the c	orrespondence add	dress			
A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION. - Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication. - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication. - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).						
Status						
1) Responsive to communication(s) filed on						
☐ This action is FINAL . 2b)☐ This action is non-final.						
3) Since this application is in condition for allowan						
closed in accordance with the practice under E	closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11, 453 O.G. 213.					
Disposition of Claims						
4) Claim(s) <u>1-23</u> is/are pending in the application.						
4a) Of the above claim(s) is/are withdrawn from consideration.						
5) Claim(s) is/are allowed.						
6)☐ Claim(s) is/are rejected.						
7) Claim(s) is/are objected to.						
8)⊠ Claim(s) <u>1-23</u> are subject to restriction and/or e	lection requirement.					
Application Papers						
9)☐ The specification is objected to by the Examiner	ſ.					
10) The drawing(s) filed on is/are: a) accepted or b) objected to by the Examiner.						
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).						
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).						
11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.						
Priority under 35 U.S.C. § 119						
 12) Acknowledgment is made of a claim for foreign a) All b) Some * c) None of: 1. Certified copies of the priority documents 2. Certified copies of the priority documents 3. Copies of the certified copies of the priori application from the International Bureau * See the attached detailed Office action for a list of 	s have been received. s have been received in Application ity documents have been received (PCT Rule 17.2(a)).	on No ed in this National S	Stage			
Attachment(s)						
Notice of References Cited (PTO-892) Notice of Draftsperson's Patent Drawing Review (PTO-948)	4) Interview Summary Paper No(s)/Mail Da					
3) Information Disclosure Statement(s) (PTO/SB/08)	5) 🔲 Notice of Informal P					
Paper No(s)/Mail Date	6)					

Application/Control Number: 10/598,965 Page 2

Art Unit: 1639

DETAILED ACTION

Status of the Claims

1. The preliminary amendment received on September 15, 2006 amended claims 3, 7, 16-18, and 23.

Claims 1-23 are currently pending and under consideration.

Election/Restrictions

2. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1-7, drawn to a combinatorial protein library.

Group II, claim(s) 8, drawn to a combinatorial expression library.

Group III, claim(s) 9-16, drawn to a mutant protein.

Group IV, claim(s) 17-23, drawn to a method for identifying a toxic ligand.

3. The inventions listed as Groups I-IV do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: the common technical feature is a mutant protein comprising an insert in the protease-sensitive loop of the A chain of a toxic protein. Wong et al. U.S. Patent Application Publication 2002/0058615 (published May 16, 2002) teach composition comprising bacteria-derived toxins including A chain toxins and inserting peptides into disulfide loops (please refer to the entire specification particularly paragraphs 12, 32, and 56). In addition, Fitzgerald U.S. Patent 7,314,632 (filed July 10, 1998) teach Pseudomonas exotoxin A-like chimeras wherein the disulfide loop has an insertion (please refer to the entire specification particularly Figures 1A and 1B; columns 2-3, 5, 16, 19).

4. This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The species are as follows:

For Group I: a single, specific species of where the insert is introduced (see claims 4-6);

For Group III: a single, specific species of where the insert is introduced (see claims 11-

12 and 15) and a single, specific species of insert (see claims 13-14); and

For Group IV: a single, specific species of how the target/receptor is displayed (see claims 20-22).

- 5. Applicant is required, in reply to this action, to elect a single species to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.
- 6. Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).
- 7. The claims are deemed to correspond to the species listed above in the following manner:

Application/Control Number: 10/598,965

Art Unit: 1639

For Group I: see claims 4-6, for Group III: see claims 11-15, and for Group IV: see claims 20-22.

8. The following claim(s) are generic: for Group I: claim 1, for Group III: claim 9, and for Group IV: claim 17.

Page 4

- 9. The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons: the species are structurally and/or functionally different.
- 10. Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement may be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.
- 11. The election of an invention or species may be made with or without traverse. To preserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.
- 12. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Application/Control Number: 10/598,965 Page 5

Art Unit: 1639

Future Communications

Any inquiry concerning this communication or earlier communications from the examiner should be directed to AMBER D. STEELE whose telephone number is (571)272-5538. The examiner can normally be reached on Monday through Friday 9:00AM-5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low can be reached on 571-272-0951. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Amber D. Steele/ Patent Examiner, Art Unit 1639

February 17, 2009